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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,802	10/23/2003	Ivo Franci Eggen	O 2000.662 USD2	2360
31846	7590 06/16/2004		EXAMINER	
111201.0	BEL PHARMA PATENT	EPPERSON, JON D		
29160 INTERVET LANE MILLSBORO, DE 19966			ART UNIT	PAPER NUMBER
			1639	
			DATE MAILED: 06/16/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/693,802	EGGEN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Jon D Epperson	1639				
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet w	ith the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reg. If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	.136(a). In no event, however, may a r ply within the statutory minimum of thin d will apply and will expire SIX (6) MON te, cause the application to become AE	reply be timely filed  ty (30) days will be considered timely.  ITHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on						
•	Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) ⊠ Claim(s) <u>1-49</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) is/are objected to. 8) ⊠ Claim(s) <u>1-49</u> are subject to restriction and/or	awn from consideration.	•				
Application Papers						
9)☐ The specification is objected to by the Examin	er.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the	J. ,	( )				
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E		• • • • • • • • • • • • • • • • • • • •				
Priority under 35 U.S.C. § 119		•				
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat * See the attached detailed Office action for a list	nts have been received. Its have been received in A Ority documents have been au (PCT Rule 17.2(a)).	pplication No received in this National Stage				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) 🔲 Interview S	Summary (PTO-413)				
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date</li> </ul>	Paper No(s	s)/Mail Date nformal Patent Application (PTO-152)				

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## **DETAILED ACTION**

## Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 28-46 and 48-49, drawn to a method for "rapid solution synthesis of a peptide in an organic solvent", classified variously, for example, in class 530, subclass 334.
  - II. Claims 47, drawn to a method for the combinatorial synthesis of peptide libraries, classified variously in class 435, subclass 6, DIG 46.
- 2. The inventions are distinct, each from the other because of the following reasons:
- 3. Groups I-II represent separate and patentably distinct inventions. Groups I-II are drawn to different methods (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). For example, Group II requires materials and methods for "combinatorial synthesis", which are not required by Group I. Different reagents, materials and method steps are required to produce a combinatorial library and a library is also used for a different purpose than a single compound. Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art

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anticipating or rendering obvious each of the above-identified groups respectively would

not necessarily anticipate or render obvious another group, because they are drawn to

different inventions that have different distinguishing features.

4. These inventions have acquired a separate status in the art as shown by their

different classification (see paragraph 1) and/or divergent subject matter. The different

methods and products would require completely different searches in both the patent and

non-patent databases, and there is no expectation that the searches would be coextensive.

Therefore, this does create an undue search burden, and restriction for examination

purposes as indicated is proper.

Species Election

5. This application contains claims directed to patentably distinct species of the

claimed invention for Groups I-II. Election is required as follows.

6. If applicant elects any of Groups I-II, applicant is required to elect from the

following patentably distinct species. Claims 1 and 47 are generic for Groups I and II,

respectively.

Subgroup 1: Species of amine scavenger (e.g., see claim 1)

Applicant must elect, for the purposes of search, a *single species* of amine scavenger. Applicants are respectfully requested to confirm their previous

election i.e., benzyl β-alaniate (see 10/23/2003 Response, page 6).

Subgroup 2: Species of extraction reagents (e.g., see claim 42)

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Applicant must elect, for the purposes of search, a *single species* of extraction reagents e.g., sodium chloride.

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Subgroup 3: Species of organic solvent (e.g., see claim 44)

Applicant must elect, for the purposes of search, a *single species* of organic solvent e.g., ethyl acetate.

Subgroup 4: Species of temperature (e.g., see claim 45)

Applicant must elect, for the purposes of search, a *single species* of temperature e.g., ambient.

- 7. Please Note: Applicants must disclose which claims read on the elected species (see paragraphs 11 and 12 below).
- 8. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.
- 9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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- 10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
- 11. Applicant is advised that a reply to this requirement <u>must include an</u>

  <u>identification of the species that is elected consonant with this requirement</u>, <u>and a</u>

  <u>listing of all claims readable thereon, including any claims subsequently added</u>. An argument that a claim is allowable or that all claims are generic is considered

  <u>nonresponsive</u> unless accompanied by an election.
- 12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, *applicant must indicate which are readable upon the* elected species. MPEP § 809.02(a).
- 13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex.

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a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

- Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 15. Applicant is also reminded that a 1 month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).
- 16. Finally, Applicant is reminded that where applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are

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governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D. June 11, 2004

BENNETT CELSA